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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,493	12/05/2003	Jun Watanabe	Q78867	7236

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EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/727,493	WATANABE ET AL.	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 13 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,115,807 ("Pless et al.") in view of U.S. Patent No. 5,249,573 ("Fincke").

As described in the Office Action mailed 3/13/06, Pless et al. discloses a defibrillator for applying electric stimulation to a living body. The defibrillator inherently includes a plurality of electrodes adapted to be attached on the living body and through which an electric pulse is output as the electric stimulation. An analyzer detects a continuous change of a voltage of the electric pulse which has been actually output from the electrodes and analyzes a parameter (following the defibrillation shock, the microprocessor calculates and displays the delivered energy and the amount of resistance by measuring the residual voltage on the discharge capacitor; see col. 11, line 45 - col. 12, lines 43) of a waveform of the electric pulse. These parameters are displayed on a display (see col. 12, lines 32-34). Pless et al. determines the displayed parameters by measuring the residual voltage on the discharge capacitor, and thus fails to disclose that the microprocessor is operable to measure a continuous change of a

voltage of the electric pulse that has actually been output from the electrodes. Fincke et al. discloses an external defibrillator having a microprocessor that measures continuous changes of a voltage of the electric pulse that has actually been output from the electrodes (by sampling a voltage sense line 146). Fincke et al. teaches that these voltage values may be utilized for determining in various parameters values relating to the delivered electric pulse such as peak current, resistance, or pulse energy (see, for example, col. 9, lines 14-34). Fincke et al. also discloses that further waveform analysis may include determining the pulse width of the delivered electric pulse, and the rise and fall times of the waveform based on the voltage sample values (see col. 13, lines 6-10). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the defibrillator of Pless et al. to include a microprocessor which is operable to detect a continuous change of a voltage of the electric pulse which has actually been output from the electrodes as taught by Fincke et al. in order to provide the defibrillator with the capability of performing further waveform analysis such as determining the actual pulse width of the delivered electric pulse and the rise and fall times of the waveform, in addition to the capability of determining the delivered pulse energy or resistance.

With respect to claim 14, Pless et al. discloses an energy charging element (capacitor 34) having terminals, in which an electric energy to be supplied to the electrodes is charged (see Fig. 1 and associated text).

3. Claims 1-2, 4-7, 9-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,115,807 ("Pless et al.") in view of U.S. Patent No. 5,249,573 ("Fincke"), and further in view of Japanese Patent Publication No. 54-112589A.

As discussed above, Pless et al. discloses a defibrillator for applying electric stimulation to a living body. The defibrillator inherently includes a plurality of electrodes adapted to be attached on the living body and through which an electric pulse is output as the electric stimulation. An analyzer detects a waveform of the electric pulse that has been actually output from the electrodes and analyzes a parameter (following the defibrillation shock, the microprocessor calculates and displays the delivered energy and the amount of resistance by measuring the residual voltage on the capacitor; see col. 11, line 45 - col. 12, lines 43) of the waveform. These parameters are displayed on a display (see col. 12, lines 32-34).

Pless et al. determines the displayed parameters by measuring the residual voltage on the discharge capacitor, and thus fails to disclose that the microprocessor is operable to measure a continuous change of a voltage of the electric pulse that has actually been output from the electrodes. Fincke et al. discloses an external defibrillator having a microprocessor that measures continuous changes of a voltage of the electric pulse that has actually been output from the electrodes (by sampling a voltage sense line 146). Fincke et al. teaches that these voltage values may be utilized for determining in various parameters values relating to the delivered electric pulse such as peak current, resistance, or pulse energy (see, for example, col. 9, lines 14-34). Fincke

et al. also discloses that further waveform analysis may include determining the pulse width of the delivered electric pulse, and the rise and fall times of the waveform based on the voltage sample values (see col. 13, lines 6-10). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the defibrillator of Pless et al. to include a microprocessor which is operable to detect a continuous change of a voltage of the electric pulse which has actually been output from the electrodes as taught by Fincke et al. in order to provide the defibrillator with the capability of performing further waveform analysis such as determining the actual pulse width of the delivered electric pulse, and the rise and fall times of the waveform.

Pless et al. also fails to disclose that the parameters are displayed together with the waveform of the electric pulse. Displaying the actual energy delivered to the patient, as well as the patient's electrical resistance, indicates to the physician whether there is a problem with the electrode system and thus alerts the physician to a problem compromising the patient's safety (see col. 5, lines 34-49). As admitted in applicant's specification, Japanese Patent Publication No. 54-112589A teaches a defibrillator that displays an output voltage waveform applied to a living body (see page 2 of applicant's specification, or see page 2, upper right corner, lines 40-41 and Fig. 3 of Japanese Patent Publication No. 54-112589A). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the display system of Pless et al. to display the output voltage waveform applied to the patient as taught by Japanese Patent Publication No. 54-112589A in order to enabling checking/verification of the output voltage waveform in addition to providing the physician with the

parameters values for checking/verifying the electrode system. Further, by displaying both the parameters and the waveform of the output voltage, the physician may make intelligent decisions regarding subsequent energy pulses.

With respect to claim 2, Pless et al. discloses an energy charging element (capacitor 34) having terminals, in which an electric energy to be supplied to the electrodes is charged (see Fig. 1 and associated text).

With reference to claims 4 and 9, Pless et al. discloses displaying parameters including the energy output by the electric pulse and a resistance between the electrodes (the electrical resistance of the patient) (see col. 11, line 45 - col. 12, lines 43).

With respect to claims 6 and 11, Pless et al. fails to disclose a plurality of housings which house the defibrillation paddles/electrodes and a resistor connected between the housings such that terminals of the defibrillation paddles/electrodes are exposed at the housings, wherein the defibrillation paddles/electrodes are electrically connected via the resistor when located in the housings. Fincke discloses a defibrillation discharge test mode, in which the defibrillation paddles are stored in a well 162 such that electrodes 160 contact a shorting bar 166. A defibrillation pulse is discharged across a short circuit, rather than the thoracic resistance of a patient, to test the defibrillation discharge circuit's functionality (see Fig. 8 and associated text). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the defibrillator of Pless et al. to include such a defibrillation discharge test mode in order to frequently test the defibrillation discharge circuit's

functionality due to the critical nature of the emergency situations in which a defibrillator is needed.

With reference to claim 5 and 10, Pless et al. discloses storage (i.e., microprocessor board 20 includes program ROM and RAM, see col. 6, lines 33-35) that necessarily stores the calculated parameters (after defibrillation, the microprocessor calculates the delivered energy and the amount of resistance; see col. 6, lines 46-57). Examiner considers the parameters to be "stored" because the parameters are necessarily at least temporarily stored in order for the microprocessor to display the parameters in blocks 88 and 90 (see blocks 88 and 90 in Fig. 2). In the alternative, Examiner notes that it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to utilize the memory capability of Pless et al. to store the calculated parameters in order to enable the defibrillator to display the parameters and/or to later access such information.

With reference to claim 7 and 12, Pless et al. discloses a defibrillator.

4. Claims 3 and 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,115,807 ("Pless et al.") in view of U.S. Patent No. 5,249,573 ("Fincke"), and further in view of Japanese Patent Publication No. 54-112589A, and further in view of U.S. Patent No. 5,713,937 ("Nappholz").

Pless et al. and Japanese Patent Publication No. 54-112589A fail to disclose the use of index marks on the display which corresponding to the detected parameters. Nappholz teaches the use of indicia which reveal, quantify, and explain various

parameters (see Fig. 5). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the display (90) of Pless et al. to include such indicia in order to visually correlate the displayed parameters with the displayed waveform.

Response to Arguments

5. Applicant's arguments with respect to claims 1-14 have been considered but are not persuasive.

6. Applicant first argues that one skilled in the art would not have been motivated to combine the teachings of Pless and Finke in order to provide a defibrillator with increased waveform analysis in addition to the ability to determine the delivered pulse energy or resistance because one would not look to the test circuit of Fincke for a solution to the problems of Pless (which is directed to the assessment of arrhythmias and defibrillation thresholds) (see pages 7-9 of Response filed 7/11/06). Examiner respectfully disagrees. Both references teach defibrillators that include microprocessors for measuring relevant parameters, such as discharge circuit current level or load resistance. Although Pless may be concerned with assessment and termination of arrhythmias, Pless is also concerned with measuring and displaying information parameters regarding defibrillation shocks (see Abstract). By measuring the residual voltage on the discharge capacitor of the defibrillator, Pless et al. teaches that it is desirable to measure and display various parameters (including the actually energy delivered to the patient and patient's electrical resistance) to the physician in order to

alert the physician of any problems compromising the patient's safety (see col. 5, lines 37-46). The defibrillator of Fincke et al. is also concerned with measuring information parameters regarding defibrillation shocks, and samples a voltage sense line 146 in order to measure various parameters values relating to the delivered electric pulse such as peak current, resistance, or pulse energy (see, for example, col. 9, lines 14-34), as well as the pulse width of the delivered electric pulse, and the rise and fall times of the waveform based on the voltage sample values (see col. 13, lines 6-10). Examiner maintains that one of ordinary skill in the art would be motivated to modify the defibrillator of Pless et al. to measure a continuous change of a voltage of the electric pulse which has actually been output from the electrodes as taught by Fincke et al. in order to provide the defibrillator with the capability of performing further waveform analysis such as determining the actual pulse width of the delivered electric pulse and the rise and fall times of the waveform, in addition to the capability of determining the delivered pulse energy or resistance. Since Pless teaches that measurement and display of various parameters regarding defibrillation shocks are desirable, one of ordinary skill in the art would be motivated to modify the microprocessor of Pless such that more parameters are measured and displayed to the physician.

7. Applicant next argues that even if the teachings of Pless and Fincke may be combined, the combination still does not teach an analyzer which measures a continous change of voltage of the electric pulse which has actually been output (see page 9 of Response filed 7/11/06). Rather, Applicant states that Fincke only samples voltages on

a voltage sense line at certain isolated times. However, Examiner considers "measure a continuous change of a voltage" to encompass sampling the voltage sense line over the duration of the capacitor discharge. Such continuous sampling provides a measurement of how the voltage values change as the electric pulse is output from the electrodes.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK
8/18/06

George Manuel
Primary Examiner